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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,155	12/07/2001	Walter A. Nichols	033018-078	9860

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EXAMINER
WEISS JR, JOSEPH FRANCIS

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/005,155	Nichols et al
Examiner	**Art Unit**
Joseph Weiss	3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Dec 7, 2001 .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-39 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-39 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 20 Mar 02 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

2.The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because applicant sets forth the use of a pre-determined "fluid" which is expelled through an outlet when the "fluid" in the chamber is volatilized by the heater. Volatilization by definition is the transfer of a material in a liquid (a sub set of fluid) or solid state into a gaseous/vapor state. Furthermore all of this is occurring under the rubric of the device "aerosolizing" the fluid. But since fluid can also be a material already in a gaseous/vapor state and which would not be subject to "aerosolization" applicant must really mean "liquid" and not "fluid" hence the usage of the terminology results in a lack of definity. Correction is required.

In regards to claims 1 & 13, applicant sets forth an element for forming the outlet, yet the language of claim 1 positively claims the existence of an outlet as a structural component of the device. This recitation in claim 13, contradicts this positive claiming of claim 1. Is there or is there not an outlet in the sub-combination device in claim 1. If there is not, and the only way an outlet can exist is by operation of the combination as some stage of its use, then the positive claiming of an outlet in claim 1 is improper and indefinite.

Furthermore claim 13, is indefinite by use of the term "and/or" because it is indeterminate as to what the scope of the claim is by use of both the conjunctive and disjunctive "and/or".

Claim 21 is indefinite by use of the term "and/or" because it is indeterminate as to what the scope of the claim is by use of both the conjunctive and disjunctive "and/or".

Claim 23 is indefinite by use of the term "and/or" because it is indeterminate as to what the scope of the claim is by use of both the conjunctive and disjunctive "and/or".

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2, 5-7, 10-12, 17, 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Lindsey (US 4012472).

In regards to claim 1, Lindsey discloses a disposable aerosol generator (101/131, see any fig) for use with an inhaler device (~107, See figs 6-9) which includes a heater (147) adapted to volatilize fluid stored in the disposable aerosol generator, comprising: a disposable body (101/131) including a sealed chamber (interior of 101/131) and an outlet (123), the disposable body including first and second layers of material defining the chamber (117/115; 135/133), the chamber accommodating a predetermined volume of a fluid which is expelled through the outlet when the fluid in the chamber is volatilized by the heater (note figs 10 & 11 showing this intended result).

In regards to claim 2, Lindsey discloses the outlet located at an end of a flow passage (103) located between the first and second layers of material.

In regards to claim 5, Lindsey discloses the first layer of material (117/135) comprises a polymer material wherein the chamber comprises a recess in the polymer material, the manner with which the chamber is made (injection molding) not further limiting by dint of the fact the claims are drawn to an apparatus and not a method and the method of making imparts to additional/patently distinguishing structure.

In regards to claim 6, Lindsey discloses the first layer of material comprises a polymer material and the second layer of material comprises a foil layer heat sealed to the polymer layer (col. 3 lines 57-62).

In regards to claim 7 Lindsey discloses the outlet located at an end of a flow passage (103) extending from the chamber, the flow passage comprising a channel in the polymer layer.

In regards to claim 10, Lindsey discloses an inhaler device (Fig 6-9) usable with the disposable aerosol generator according to claim 1, wherein the inhaler device includes a heater arranged to heat the fluid in the chamber (147) so as to expel volatilized fluid from the outlet.

In regards to claim 11, Lindsey discloses the heater as an electrical resistance heater (Col. 9 lines 1-5).

In regards to claim 12 Lindsey discloses the heater comprises a layer of resistance heating material on a substrate (wire over-wrap of heating element), the substrate including an opening located adjacent the outlet (211).

In regards to claim 17, Lindsey discloses a dispensing member (111) located adjacent the outlet of the aerosol generator, the volatilized fluid expelled from the outlet passing through a passage in the dispensing member (note figs 10-11).

In regards to claim 25 Lindsey discloses the sealed chamber comprises a reservoir in a lower surface of the disposable body (formed by "lower surface" of 117) and a flow passage (103) in an upper surface of the disposable body (upper surface of 117 at its perimeter), the flow passage being in fluid communication with the reservoir.

In regards to claim 26, Lindsey discloses a first layer of material (117) on the lower surface covers the reservoir and a second layer of material (115) on the upper surface covers the flow passage, the disposable body comprising a polymer material, the first layer of material comprising a polymer film and the second layer of material comprising a heat resistant material. (Note the disclosure of Lindsey on the materials used for layers 115/117, note the relative nature

of the language "resistant" hence any material is considered to have some level of "resistance to heat).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 3-4, 9, 15, 18-19, 20-24, 27-33 & 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsey.

In regards to claim 3, Lindsey discloses a disposable body that fits in the inhaler, but does not disclose the disposable body having a "series of aerosol generators", i.e the duplication of a known part for a known purpose.

It is noted that applicant's specification does not set forth this variation of what is known in the art, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to the device being configured to allow advancement of the aerosol generators to a release point, one of ordinary skill would consider such to be an obvious and necessary configuration when duplicating the aerosol generators in a single disposable body, and hence not constitute a patently distinct inventive step.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 4, the prior art discloses such for a single aerosol generator and hence when duplicating, such features would likewise be duplicated.

In regards to claim 9, Lindsey discloses substantially disclose the claimed invention to include the channel being rectilinear but does not include the specific sizing of the channel.

It is noted that applicant's specification does not set forth this specific sizing, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 15, the disposable body of Lindsey is fully capable of being movably supported into a release position.

In regards to claim 16, Lindsey discloses the layer of resistance heating material comprises a strip (wire over-wrap) arranged in a pattern, but does not "size" the pattern of over-wrap to be coextensive with the size of the chamber.

It is noted that applicant's specification does not set forth this variation of what is known in the art, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 18, the rejection to claims 3-4 is herein incorporated by reference.

In regards to claim 20, Lindsey discloses the disposable body includes a flow passage extending rectilinearly from the chamber (103), but does not disclose the heater arranged to heat both the chamber & the flow passage with a layer of resistance material that facilitates one portion of the heater to be become "hotter" than the other portion.

It is noted that applicant's specification does not set forth this reversal/rearrangement of know parts for a known purpose, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 27, one of ordinary skill would consider the use of a plurality of chambers to constitute a mere obvious duplication of a known part for a known purpose and further that the features of a disc form with gear teeth on the periphery to be old and well known.

In regards to claim 29, Lindsey discloses the inhaler device comprises a housing (107) and a cover (143), the cover being movable with respect to the housing so as to permit insertion of the disposable body in the inhaler device when the cover is in an open position.

In regards to claim 31, Lindsey discloses the inhaler device including a fluid delivery mechanism (See fig 10 & supporting text regarding pressurization of the chamber to push liquid to the heater) which engages the disposable body such that fluid in the chamber is forced out of the chamber, along a flow passage (103) in the disposable body and toward the outlet, the heater being arranged to heat the liquid in the flow passage.

In regards to claim 32, the reference noted above substantially disclose the claimed invention to include a pressurized oxygen source but does not disclose the use of a piston as the means for pressurizing the fluid in the chamber to sent it to the inhaler for aerosolization.

It is noted that applicant's specification does not set forth the use of a piston as the means for pressurizing, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 33, the reference noted above substantially disclose the claimed invention to include a pressurized oxygen source but does not disclose the use of all the mechanical support elements for a piston as the means for pressurizing the fluid in the chamber to sent it to the inhaler for aerosolization.

It is noted that applicant's specification does not set forth the use these standard piston support mechanics, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to method claims 21-24 & 37-39, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the

device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claims 1-20 & 25-36.

8. Claims 13, 14, 19, 28, 30, 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsey as applied to claims 12, 18, 29 & 33 above, and further in view of Jackson (US 6116238) .

In regards to claims 13, 14, 19, 28, 30, 34-36, Lindsey substantially discloses the instant application's claimed invention, but does not explicitly disclose an opening/pierce (manual or automated) and lifting/advancement element. However, Jackson disclose such (pierce/lift element 150, spindle 48, note the use of automation of operation) . The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Jackson and used them with the device of Lindsey. The suggestion/motivation for doing so would have been to use the device in a discrete, automated repetitive dosing manner. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature, and all remaining features that flow from such feature, its usage and arrangement is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No. 09/742321. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a disposable aerosol generator comprising a disposable body having a sealed chamber, an outlet, the body having first and second layers of material that define the chamber with the intended uses/results of retaining a pre-

determined amount of fluid (Liquid) that is volatilized and expelled from the outlet using a heater, an inhaler for use with such an aerosol disposable generator the inhaler comprising a heater arranged to heat the chamber so as to expel volatilized fluid from the outlet, and method of operation of the combination of the inhaler & aerosol generator.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

Regarding claim 8, the unifying basis for allowability being that in terms of inventive concept of having a blister pack with a plurality of blisters with liquid materials within them and sufficient structure present to facilitate controlled aerosol deliver of the liquid medicament from the blister in a controlled manner (a plurality of channels as illustrated in the blister disc surface?) by dint of the application of heat. I.e. any multi dose blister pack could contain and deliver liquid medicament in an aerosol form by dint of heating, but this would be purely due uncontrolled rupture of the blister when heated, no design has taken place to control the deliver, but merely punching a hole in the blister would not suffice (See Kafer & Lin).

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6481437, 6378518, 6367473, 6250301, 6131570, 6053176, 6028293, 6020575, 5934099, 5792422, 5743251, 5115911, 4753352, 4457327, 4342395, 4012473, 4012471

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Weilun Lo, can be reached at telephone number (703) 308-1957. The official fax number for this group is (703) 305-3590 or x3591.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.

JFWeiss

February 4, 2003

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